

Appl. No.: 09/867,948

Filed: May 30, 2001

Page 2

REMARKS

Status of the Claims

Applicants note the withdrawal of the previous rejection under 35 U.S.C. § 102 over Rupp *et al.*, GB 2153830. Claims 1 and 3-6 are pending. Reconsideration of the claims is respectfully requested in view of the following remarks. The Examiner's comments in the Office Action are addressed below in the order set forth therein.

The Rejections of the Claims under 35 U.S.C. § 102(b) Should Be Withdrawn

Claims 1 and 3-6 stand rejected under 35 U.S.C. § 102(b) over Reuveny *et al.* (1986) *J. Immunol. Methods* 86:53-59. The rejection is respectfully traversed.

The Office Action states that Reuveny *et al.* teach a method of increasing monoclonal antibody production by growing host cells in 25% dissolved oxygen (DO), as opposed to growing the cells at a normal concentration of 60% DO. Reuveny *et al.* is not an anticipatory reference, as explained in the following paragraphs.

An anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device. *In re Donohue*, 766 F.2d 531, 534, 226 USPQ 619, 621 (Fed. Cir. 1985). Claim 1 of the present application is directed to the following:

A method of determining the optimal level of product expression in animal cell culture wherein the concentration of a solute of interest in a culture medium composition for optimal product expression is different than the concentration of said solute in the culture medium composition determined for optimal cell growth, which method comprises:

- a) growing the animal cell culture in a culture medium to determine optimal cell growth;
- b) varying the concentration of the solute in the culture medium to a concentration above that optimal for cell growth, which concentration is effective to create an environment of solute stress on the cell culture as expressed by an inhibitory effect on cell growth or cell density of said cell culture;
- c) monitoring the product expression as concentration of the solute is varied in the culture medium to determine optimal product expression; and
- d) selecting the solute concentration that provides the optimal combination of cell growth and product expression, which allows for optimal productivity.

Appl. No.: 09/867,948

Filed: May 30, 2001

Page 3

In particular, claim 1 recites "varying the concentration of the solute in the culture medium to a concentration *above* that optimal for cell growth, which concentration is effective to create an environment of solute stress on the cell culture..." (emphasis added). Applicants' specification states that "'solute stress' refers to the addition of solutes in such concentrations, at least above that concentration determined for optimal cell growth, that produce a growth inhibitory effect or reduced final cell density, that is, a growth rate or maximum cell density less than that determined for optimal growth." See page 6, lines 12-18.

In contrast to claim 1, Reuveny *et al.* teach a method in which DO is varied to a concentration *below* that optimal for cell growth (25% DO, as opposed to the optimal 60% DO). See Reuveny *et al.*, paragraph spanning pages 55-56. Therefore, Reuveny *et al.* does not create an environment of solute stress on the cell culture in the manner set forth in claim 1.

For these reasons alone, Reuveny *et al.* does not teach the limitations of claim 1 and, consequently, does not anticipate claim 1. Because each of claims 3-6 depend from claim 1, Reuveny *et al.* does not anticipate claims 3-6. Accordingly, the rejection of claims 1 and 3-6 should be withdrawn.

CONCLUSION

In view of the aforementioned amendments and remarks, Applicants respectfully submit that the rejection of the claims under 35 U.S. C. § 102 is overcome. Accordingly, Applicants submit that this application is now in condition for allowance. Early notice to this effect is solicited.

Appl. No.: 09/867,948

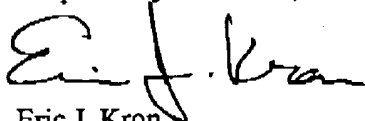
Filed: May 30, 2001

Page 4

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



Eric J. Kron
Registration No. 45,941

Customer No. 00826

ALSTON & BIRD LLP

Bank of America Plaza

101 South Tryon Street, Suite 4000

Charlotte, NC 28280-4000

Tel Raleigh Office (919) 862-2200

Fax Raleigh Office (919) 862-2260

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the US Patent and Trademark Office at Fax No. (703) 872-9306 on the date shown below.



Pamela Lockley

March 19, 2004

Date

RTA01/2151800v1